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Docket No. 2551-1-001N

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Hassan Ahmad &  
Ismail Elchagea

EXAMINER: McCormick Ewoldt, Susan Beth

SERIAL NO.: 10/662,777

ART UNIT: 1654

FILED: September 12, 2003

FOR: BOTANICAL DRUG COMPOSITIONS FOR TREATMENT OF  
LIVER AND IMMUNOLOGICAL DISORDERS

**CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 23, 2005.

Loretta Kavanagh  
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Loretta Kavanagh 11/23/05  
Signature of person signing Certificate

INTERVIEW SUMMARY

COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VA 22313-1450

Sir:

A Final Office Action for the above-noted application was mailed on September 7, 2005. Following receipt of this Office Action, Applicants' agent of record, Veronica Mallon, requested a telephonic interview with the Examiner. Such telephonic interview transpired on October 24, 2005.

During the interview, Dr. Mallon clarified what Applicants believe to be the differences between the references cited in the Office Action (Shawkat and Medenica) and the present invention as claimed. More specifically, Drs. Hassan Ahmad and Ismail Elchagea pointed out to the Examiner the fact that the compositions as claimed were to be used for treating advanced stage hepatitis patients, for which no other therapies exist.

The Examiner clarified that the intended use did not differentiate between the cited reference and Applicants' invention since the method claims are not currently under examination. The Examiner noted that while the intended use may be different, Applicants must further differentiate between the composition as claimed and the cited references.

Applicants' representative then pointed out that the response to the Final Office Action would include amendments to the claims that would differentiate the composition of Applicants from the references cited. More importantly, Applicants' representative noted that the response to the first Office Action, which was mailed on June 29, 2005 included a declaration under 37 CFR 1.132, signed by Dr. Ismail Elchagea, attesting to the fact that the composition as claimed provided unexpected results in that the plant extract must be used at a concentration of not less than 20%. Furthermore, it was noted by Dr. Elchagea that lower percentages were tested in advanced stage hepatitis patients, but the dramatic results observed with the higher doses were not observed with the lower doses. More specifically, it was also pointed out in the declaration and to the Examiner that the results observed in the cited references could not have shown the effects that Applicants have observed because the doses used were significantly lower than Applicants' dosage range. More importantly, it was noted by Applicants that the higher doses presently claimed by Applicants provided the unexpected finding of not just a stabilization of liver function, but a reversal of the damage to the liver observed in these patients before treatment.

Examiner Susan Coe noted that she would give further consideration to the declaration under 37 CFR 1.132 again, and that our response should include the changes we noted in the present interview along with a Request for Continued Examination.

Applicants and Applicants' representative respectfully thanked the Examiners for their time and further consideration of the pending application.

***Fees***

It is believed that no fees are necessary in connection with this submission. However, if any fees are due, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment.

***Conclusion***

Based on the foregoing discussion, Applicants submitted a response to the Final Office Action on November 3, 2005, along with a Request for Continued Examination and will wait for further and favorable action on the merits of the present application.

Respectfully submitted,



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